

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-1993V

EMILY SMITH,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: March 22, 2024

Paul R. Brazil, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Emilie Williams, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE¹

On December 28, 2020, Emily Smith filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*² (the “Vaccine Program”). Petitioner alleges that she suffered a shoulder injury related to vaccine administration (“SIRVA”) as a result of a hepatitis B (“hep B”) vaccine administered to her on December 27, 2019. Petition (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”). Based on Respondent’s opposition and careful review of the entirety of Petitioner’s submissions, I find that there is not preponderant evidence that the alleged injury or its residual effects or complications persisted for at least six months post-vaccination. See Section

¹ Because this unpublished decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims’ website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

11(c)(1)(D)(i). Therefore, her claim is not eligible to proceed within the Vaccine Program, and it must be dismissed.

I. Procedural History

The December 2020 petition was initially supported by affidavits from Petitioner, Ex. 1, and from her counsel, Ex. 2 (averring that the petition was filed prior to Respondent's anticipated declassification of SIRVA as a Table injury).³ Most of the required medical records were filed as Exs. 3 – 7 in September 2021 (ECF No. 12), followed the case's assignment to SPU in February 2022 (ECF No. 18), and one final set of outstanding medical records as Ex. 8 in April 2022 (ECF No. 23).

On May 24, 2023, Respondent filed his Report pursuant to Vaccine Rule 4(c) in which he recommended dismissal on the grounds that Petitioner could not satisfy the statutory severity requirement. Rule 4(c) Report (ECF No. 33) at 5-6. On August 8, 2023, Petitioner was directed to show cause why her case should not be dismissed for that reason. Show Cause Order (ECF No. 35).

On October 10, 2023, Petitioner filed sworn fact witness statements as Exs. 9 – 12 (ECF No. 36),⁴ and a brief averring that her injury was eligible for the Program. Show Cause Response (ECF No. 37). The matter is now ripe for adjudication.

II. Authority

The petitioner carries the burden of establishing the matters required in the petition by a preponderance of the evidence. Section 13(a)(1)(A). One such requirement is documentation demonstrating severity – generally, that the injured party “suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” Section

³ On July 20, 2020, the Secretary of Health and Human Services proposed the removal of SIRVA from the Vaccine Injury Table. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Proposed Rule*, 85 Fed. Reg. 43794 (July 20, 2020). The proposed rule was finalized six months later. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Final Rule*, 86 Fed. Reg. 6249 (Jan. 21, 2021). Approximately one month later, the effective date for the final rule was delayed. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Delay of Effective Date*, 86 Fed. Reg. 10835 (Feb. 23, 2021) (delaying the effective date of the final rule until April 23, 2021). On April 22, 2021, the final rule removing SIRVA from the Vaccine Table was rescinded. *National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Withdrawal of Final Rule*, 86 Fed. Reg. 21209 (Apr. 22, 2021).

⁴ All statements are sworn under penalty of perjury. See 28 U.S.C.A. § 1746 (providing that such a declaration may be afforded “like force and effect” as an affidavit).

11(c)(1)(D)(i)⁵; *see also Black v. Sec’y of Health & Human Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the “potential petitioner” must not only make a *prima facie* case, but clear a jurisdictional threshold, by “submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case”), *aff’d*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Congress has stated that the severity requirement was designed “to limit the availability of the compensation system to those individuals who are seriously injured from taking a vaccine.” H.R. REP. 100-391(I), at 699 (1987), reprinted in 1987 U.S.C.C.A.N. 2313–1, 2313–373, cited in *Cloer v. Sec’y of Health & Human Servs.*, 654 F.3d 1322, 1335 (Fed. Cir. 2011), *cert. denied*, 132 S.Ct. 1908 (2012); *Wright v. Sec’y of Health & Human Servs.*, 22 F.4th 999, 1002 (Fed. Cir. 2022).

The Act prohibits finding a petition requirement “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” Section 13(a)(1). Medical records must be considered, *see* Section 13(b)(1), and are generally afforded substantial weight. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). *Murphy v. Sec’y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff’d per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). However, the Federal Circuit has recently “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec’y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

It is thus certainly the case that factual matters required to prove elements of a Vaccine Act claim may be established by a *mix* of witness statements and record proof, with the special master required to fully consider and compare the medical records, testimony, and all other “relevant and reliable evidence contained in the record.” *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184 (2013) (citing Section 12(d)(3); Vaccine Rule 8), *aff’d*, 746 F.3d 1335 (Fed. Cir. 2014).

III. Medical Record Evidence

Upon receiving the subject vaccine in her left arm on December 27, 2019, (*see* Ex. 3 at 3), Petitioner had “no prior left shoulder condition.” Resp. Report at 2; *see generally* Exs. 4-5 (primary care records). She was twenty-one (21) years old, enjoyed “running

⁵ Section 11(c)(1)(D) presents two alternative grounds for eligibility to compensation if a petitioner does not meet the six months threshold: (ii) death from the vaccine, and (iii) inpatient hospitalization and surgical intervention. Neither alternative is alleged or implicated in this claim.

and lifting,” and was studying neuroscience at a university approximately one hour away from home. Ex. 8 at 114.

Thirteen (13) days post-vaccination, on January 9, 2020, Petitioner presented as a new patient to an orthopedist to address left shoulder pain “for the past 2 weeks... start[ing] on 12/27/19 after receiving her hepatitis B vaccine.” Ex. 8 at 12. She recalled that the shot had been placed “higher than usual.” *Id.* She rated her pain at 7/10, which was worsened by forward and lateral flexion, and improved by rest. *Id.* Physical exam revealed mild tenderness to palpation over the biceps tendon and lateral deltoid; 4/5 strength on several measures; mildly reduced AROM on forward flexion (170 degrees); and a positive Hawkins test (evidencing impingement). *Id.* at 13. The orthopedist suspected “an inflammatory condition localized to the L shoulder such as Parsonage-Turner syndrome.” *Id.* at 14. The orthopedist recommended rest, ice, elevation, and Naproxen to treat her pain,⁶ pending an EMG. Ex. 8 at 14; *see also id.* at 40-41 (unremarkable x-ray findings).

On January 17, 2020, Petitioner reported that her EMG had been scheduled for February 10th and her orthopedics follow-up appointment for the next day. Ex. 8 at 57. In the interim, she requested recommendations for treating her shoulder pain – noting that the Naproxen had not helped and caused gastrointestinal side effects. *Id.* She had been taking ibuprofen “when the pain is really intense, which has some effect but doesn’t help very much.” *Id.* The orthopedist recommended ibuprofen and ice, and he placed a referral for physical therapy (“PT”). *Id.* at 56.

At the February 10, 2020, EMG appointment, Petitioner reported the same history of post-vaccination shoulder pain. Ex. 8 at 68. “Following the vaccine, she had shoulder pain and difficulty with any range of motion (flexion, abduction). Symptoms began to improve about 2 weeks ago. At this time, she notes twinges of pain with donning her coat and opening the door. She returned to weight training yesterday, and noted a sensation of asymmetry when using her shoulder, without frank pain... There is mild pain over the border of the upper trapezius on the left, present only over the past few weeks.” *Id.* During this appointment, a physical exam found full strength, full range of motion with some pain, and a “mildly positive” empty can test. *Id.* The EMG found no evidence of Parsonage-Turner syndrome, neuropathy, or radiculopathy. *Id.* The orthopedist promptly acknowledged the findings. *Id.* at 69.

⁶ Within this medical record, the current medication list reflects that Petitioner was also taking butalbital-acetaminophen-caffeine tablets as needed. Ex. 8 at 3. This medication does not appear to have been newly prescribed to treat shoulder pain – and instead, seems more likely a treatment for Petitioner’s preexisting migraine headaches.

The next day, February 11, 2020, the orthopedist recorded that Petitioner's pain, range of motion, and strength were "improved since our last visit." Ex. 8 at 78. A physical exam revealed the same mild tenderness at the biceps tendon and lateral deltoid, 4/5 strength, and mildly reduced AROM on forward flexion – but a *negative* Hawkins test (previously positive). *Id.* at 80. The orthopedist's assessment was "less impingement signs[,] more signs of supraspinatus tendonitis," and shoulder weakness, for which Petitioner should undergo formal PT and follow up with him as needed. *Id.*

At the February 20, 2020, PT initial consult (also recorded as the first visit), Petitioner provided a similar history of post-vaccination shoulder pain. Ex. 8 at 114. "[The pain] lingered and got gradually worse over the past month. She states about a month ago she did notice the pain getting better, but now she feels really weak and achy. Rates pain 3-4/10 and describes it as tweaky... She would like to return to lifting weight[s] and sleeping through the night." *Id.* Physical exam of the left shoulder/arm revealed mild tenderness at the biceps tendon and lateral deltoid, 4/5 strength, and *normal* range of motion – including on forward flexion (175 degrees, equivalent to the non-injured right arm); and *no* impingement signs. *Id.* at 114 – 15. The therapist planned to improve Petitioner's left upper extremity and scapular strength. *Id.* at 115. The goals were for Petitioner to demonstrated independence with a home exercise program ("HEP"); restore "independent and safe" overhead lifting and reaching, self-care and grooming, and activities of daily living; and improve her functional score of 73/100 by at least 10%. *Id.* at 115 – 16. The therapist planned 2-3 formal sessions per week for 4 weeks – while certifying that the plan of care would "be reviewed in 30 days." *Id.* at 116; *see also id.* at 104-05 (home exercise worksheets provided to Petitioner that same day).

Petitioner returned for formal PT sessions on February 24; March 2; March 4; and March 9, 2020. Ex. 8 at 142-44, 165-66, 179-80, 202-03. The records do not specifically document whether her strength was improving or whether she was progressing towards her other goals. At the last visit on March 9, 2020, Petitioner reported that at rest, her pain level was 0/10. *Id.* at 202. But she reported difficulty putting on a shirt and opening doors, and a maximum pain level of 2-3/10. *Id.* The therapist recorded a need for "cuing to avoid excessive ant[er]ior stress on left shoulder [and...] to achieve optimal scapular retraction and stabilization." The therapist planned to "cont[inue] to progress with focus on strength." *Id.* at 203. Petitioner cancelled three further PT visits citing the emerging Pandemic. *Id.* at 215, 222, 235.

On March 25, 2020, Petitioner communicated that she was "not planning to return [to PT] at this time." Ex. 8 at 266. The therapist recorded: "Symptom[s] were unchanged

at last visit. VAS⁷ of 2-3/10. D/c due to COVID-19.” *Id.* The therapist was then prompted to select a reason for discharge. *Id.* She chose: “Patient has reached a plateau in their progress, minimal changes expected” – but wrote in, again, that the discharge was “due to COVID-19 pandemic.” *Id.* The therapist recorded that Petitioner would be discharged to continue with her independent HEP. *Id.*⁸

On January 14, 2021 – ten months later - an employee of the orthopedics practice recorded that Petitioner had “request[ed] a new PT script for continued shoulder pain.” Ex. 8 at 293. The employee questioned: “[s]he hasn’t been since 2/11/2020, is this something we could get or would she need a vv with [the orthopedist] first?” *Id.*

On January 26, 2021, the orthopedist conducted a virtual visit “for follow up of left shoulder impingement.” Ex. 8 at 300. He recorded Petitioner’s report that “pain resolved with formal PT, however in the past months, she progressed her activity to weightlifting in the gym and the pain has returned. She describes the pain as mild, lateral in location, and worse with abduction against resistance, typing on the computer, and using her phone. She denies any new symptoms at this time.” *Id.* In his assessment, the orthopedist reiterated: “[Petitioner’s] symptoms had resolved a year ago with formal physical therapy but returned when she began lifting weight in the gym again.” *Id.* He recommended home exercises; ice and NSAIDs for pain; and following up as needed. *Id.* However, there are no further medical records. Status Report filed Sept. 22, 2022 (ECF No. 28).

IV. Respondent’s Rule 4(c) Report and Show Cause Analysis

To establish the statutory severity requirement, Petitioner must demonstrate that after her December 27, 2019, vaccination, her shoulder injury persisted for at least six months – until at least June 27, 2020. Respondent argues, citing to the medical records, that “preponderant evidence demonstrates that Petitioner’s left shoulder injury... resolved less than six months post-vaccination, and that her complaints upon her return to care were likely a new injury, attributable to her weightlifting.” Rule 4(c) Report at 5.

On preliminary review, I found these arguments to be well-founded – noting that Petitioner’s pain and mild limitations in range of motion were already improving by about six weeks post-vaccination. Show Cause Order at 5. The subsequent PT records

⁷ Presumably an abbreviation for visual analogue scale – which is a measure of pain intensity. See *Visual Analogue Scale*, Physiopedia, https://www.physio-pedia.com/Visual_Analogue_Scale (last accessed Mar. 21, 2024).

⁸ Both parties suggest that Petitioner actually attended a PT session on March 25, 2020. See Rule 4(c) Report at 3; Show Cause Response at 3, 6. But there is little evidence to support that interpretation – given that the record describes only Petitioner’s *statements* to the therapist, and she had canceled three prior encounters in light of the Pandemic.

reflected further decreases in pain, and the initial PT certification was for just 4 weeks. *Id.* Although that initial PT course was cut somewhat short by the Pandemic (with a discharge on March 25, 2020), it seems more likely than not given the overall record that Petitioner's condition was highly likely to resolve fully not long thereafter. *Id.* That was followed by a nine-month gap in any medical record documentation or even patient portal messages evidencing an ongoing injury. *Id.* That gap is followed by the orthopedist's follow-up appointment which noted that Petitioner's post-vaccination pain "resolved," and then "returned when she began lifting weight in the gym again." *Id.* at 6. Such medical record documentation is typically seen as reliable – including the patient's own history therein – and the explanation for pain recurrence seemed logical in this case. *Id.* But Petitioner received a further opportunity to offer *any* further evidence and briefing.

V. Petitioner's Show Cause Response and Further Analysis

In arguing that her claim should proceed, Petitioner maintains that she was "clearly symptomatic" in March 2020, and that there is no contemporaneous evidence of a full recovery – only a "treatment gap." Show Cause Response at 6.

As previously noted in the Order to Show Cause, however, the available evidence indicates that the injury was already improving by six weeks post-vaccination, and further improved by the last formal PT session which was on March 9, 2020 – *two months and thirteen days post-vaccination*. Therefore, the available evidence suggests that Petitioner's injury would likely have fully recovered by six months post-vaccination.

Petitioner has submitted some additional statements, all prepared in October 2023. Two are unhelpful because they skip over the crucial "treatment gap" in this case (from March 2020 – January 2021).⁹ The other statements, from Petitioner and her mother, describe that the vaccine injury persisted past her March 2020 formal PT discharge, despite daily adherence to the provided home exercise program plus additional suggestions found online. Petitioner wanted additional treatment for her shoulder in fall 2020, but that was delayed because of other family members' more emergent medical concerns involving hospitalizations; financial constraints; and their high-deductible health insurance plan. These statements lack any discussion of Petitioner resuming or increasing her weightlifting regimen, or suffering any aggravation or new injury, however

⁹ A friend recalls being with Petitioner "almost every waking hour" while they were in college together, but also that they were sent home "due to COVID in March 2020." Ex. 9 at ¶¶ 1 – 3. The friend's recollections then jump forward to her "being surprised when [Petitioner] was still complaining about pain from her shoulder during the Spring 2021 semester." *Id.* at ¶ 4. Similarly, while Petitioner's former boyfriend recalls how the post-vaccination injury impacted her daily life during the spring 2020 semester, he seems to skip forward to their "catch[ing] up via a phone call in the fall of 2021." Ex. 12 at ¶ 4.

– which is the key concern identified in the Rule 4(c) Report and the Show Cause Order. See *generally* Exs. 10 – 11.

The October 2023 statements also contain some inaccuracies when compared to the contemporaneous medical record documentation. For instance, Petitioner recalls attending “about two months” of formal PT, Ex. 11 at ¶ 4, when it was actually just five formal PT sessions within a single month. Her mother’s recollection of the health insurance deductible amount is higher than what is reflected in the contemporaneous records. Compare Ex. 10 at ¶ 5 and Ex. 8 at 214. And notwithstanding the asserted concern about treatment costs, the over nine-month-gap in any contemporaneous documentation or even patient portal messages to established providers (which Petitioner had utilized in the past, and would not obviously cost anything) cuts against the allegation of an ongoing injury or residual effects.

The only other medical record evidence relevant to severity demonstrates that Petitioner’s shoulder pain had “resolved with formal PT however, in the past months, she progressed her activity to weightlifting in the gym and the pain has returned” as of January 2021. Ex. 8 at 300. Petitioner argues that the *formal* PT records ending in March 2020 do not document a full recovery, and any “resolution” should be attributed to her HEP, which continued on to some later date. Show Cause Response at 6. She also argues that the above description does not sound like a new injury, but rather, an aggravation or residual effects of the vaccine injury. *Id.* at 7. However, the overall balance of evidence weighs against this determination, and better supports the conclusion that she had recovered prior to the severity cut-off, with subsequent issues not likely attributable to any initial vaccine reaction, but instead reflective of a new, unrelated injury.

Conclusion

Petitioner has not established the statutory severity requirement. Therefore, she is ineligible to pursue compensation under the Program. In the absence of a timely-filed motion for either reconsideration or review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this Decision.¹⁰

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

¹⁰ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.